



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
College Park, MD 20740

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JUN 19 2002

Mr. Robert C. Doster  
Senior Vice President of Scientific Affairs  
PhytoPharmica Natural Medicines  
825 Challenger Drive  
Green Bay, Wisconsin 54311-8328

Dear Mr. Doster:

This is in response to your letters of June 6, 2002 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that PhytoPharmica Natural Medicines is making the following claims, among others, for the following products:

**Clinical Nutrients™ Prenatal Formula**

“...including folic acid, to help prevent birth defects...”

**Clinical Nutrients™ for Women**

“...reducing the risk of osteoporosis...”

These statements are not statements of nutritional support subject to 21 U.S.C. 343(r)(6), but are health claims subject to 21 U.S.C. 343(r)(1)(B). FDA has authorized a health claim on the relationship between folate and neural tube defects (see 21 CFR 101.79). A dietary supplement that meets the eligibility and message requirements set forth in this regulation may bear a claim for the relationship between folate and neural tube defects. A health claim for folate and neural tube defects on the label or in the labeling of a food or dietary supplement that is not in accordance with the requirements in 21 CFR 101.79 would misbrand the food or dietary supplement under 21 U.S.C. 343(r)(1)(B). Moreover, making a claim that is not in accordance with the requirements in 21 CFR 101.79 subjects the product to regulation as a drug under 21 U.S.C. 321(g)(1)(B) because the product is intended to treat, cure, prevent, or mitigate a disease, neural tube defects.

FDA has also authorized a health claim on the relationship between calcium and osteoporosis (see 21 CFR 101.72). A dietary supplement that meets the eligibility and message requirements set forth in this regulation may bear a claim for the relationship between calcium and osteoporosis. A health claim on the label or in the labeling of a food or dietary supplement that is not in accordance with the requirements in 21 CFR

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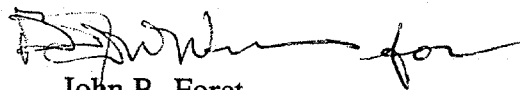
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101.72 would misbrand the food or dietary supplement under 21 U.S.C. 343(r)(1)(B). Moreover, failure to make a claim in accordance with the requirements in 21 CFR 101.72 subjects the product to regulation as a drug under 21 U.S.C. 321(g)(1)(B) because the product is intended to treat, cure, prevent, or mitigate a disease, osteoporosis.

Please contact us if we may be of further assistance.

Sincerely,

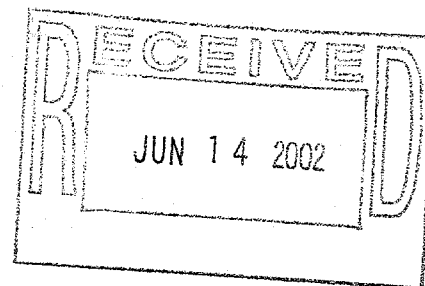
A handwritten signature in dark ink, appearing to read "John B. Foret", followed by a horizontal line and a small flourish.

John B. Foret  
Director

Division of Compliance and Enforcement  
Office of Nutritional Products, Labeling  
and Dietary Supplements  
Center for Food Safety  
and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300  
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of  
Enforcement, HFC-200  
FDA, Minneapolis District Office, Office of Compliance, HFR-MW340



June 6, 2002

Office of Special Nutritionals (HFS-450)  
 Center for Food Safety and Applied Nutrition  
 U.S. Food and Drug Administration  
 5100 Paint Branch Parkway  
 College Park, MD 20740-3835

RE: Label Claims/Disclaimers

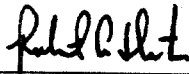
Dear Sir/Madam:

This letter is to notify you that PhytoPharmica at 825 Challenger Drive, Green Bay, Wisconsin 54311 is a distributor and has included statements provided for by section 403(r)(6) of the Food, Drug, and Cosmetic Act on the labels of the following product.

<u>COMPANY</u>	<u>PRODUCT NAME</u>	<u>DIETARY INGREDIENTS</u>	<u>STATEMENTS</u>
Phyto-Pharmica (a Division of Integrative Therapeutics Inc.)	Clinical Nutrients™ for Women	Vitamin A, Vitamin C, Vitamin D, Vitamin E, Vitamin K, Thiamin, Riboflavin, Niacin, Vitamin B6, Folic Acid, Vitamin B12, Biotin, Pantothenic Acid, Calcium, Iron, Phosphorus, Iodine, Magnesium, Zinc, Selenium, Copper, Manganese, Chromium, Molybdenum, Sodium, Potassium, Choline Bitartrate, Black Tea Leaf Extract, Cherry Fruit Extract, Green Tea Leaf Extract, Inositol, Ginger Rhizome Extract, Cranberry Fruit Extract, Chaste Tree Berry Extract, Grape Seed Extract, Bilberry Fruit Extract, Boron, Lutein, Silicon, Vanadium, Zeaxanthin	Clinical Nutrients™ for Women provides 40 key nutrients women ages 18 to 45 need to build good health, including calcium, vital for maintaining bone health and reducing the risk of osteoporosis; vitamin B6; and licorice root, involved in some of the hormonal processes of the menstrual cycle.*

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I certify that the information contained in this notice is complete and accurate and that PhytoPharmica has substantiation that the statements are truthful and not misleading.

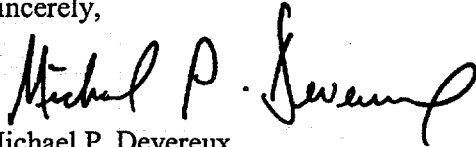
By:   
Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 6-6-02

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs, at (920) 406-3608.

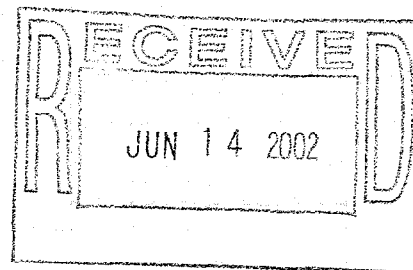
Sincerely,



Michael P. Devereux  
Chief Financial Officer



**PhytoPharmica**  
NATURAL MEDICINES™



June 6, 2002

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Phyto-Pharmica (a Division of Integrative Therapeutics Inc.)	Clinical Nutrients™ Prenatal Formula	Vitamin A, Vitamin C, Vitamin D, Vitamin E, Vitamin K, Thiamin, Riboflavin, Niacin, Vitamin B6, Folic Acid, Vitamin B12, Biotin, Pantothenic Acid, Calcium, Iron, Iodine, Magnesium, Zinc, Selenium, Copper, Manganese, Chromium, Molybdenum, Sodium, Potassium, Mixed Bioflavonoids, Choline Bitartrate, Inositol, Dandelion Root Extract, Boron, Silicon, Vanadium	Clinical Nutrients™ Prenatal Formula delivers 40 specific vitamins and minerals pregnant or nursing mothers need, including folic acid, to help prevent birth defects; beta carotene, for immune function; and vitamin B6 for increased energy during pregnancy.*

I certify that the information contained in this notice is complete and accurate and that PhytoPharmica has substantiation that the statements are truthful and not misleading.

By: Robert C. Doster

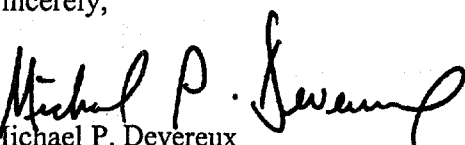
Robert C. Doster

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Sincerely,

  
Michael P. Devereux  
Chief Financial Officer